UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,622	12/10/2004	Joan Roig Amores	MGH-006.1P US	2699

7590 01/29/2007

Leon R Yankwich
Yankwich & Associates
201 Broadway
Cambridge, MA 02139

EXAMINER	
REDDIG, PETER J	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,622	ROIG AMORES ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 1 and 2 link inventions 1 and 2. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP ' 804.01.

Group 1, claim(s) 3-16, drawn to a cell free method of identifying a compound, as disclosed in the specification that is an inhibitor of mitosis comprising the steps of: (a) providing a kinase reaction mixture comprising a purine nucleoside triphosphate, a Nercc1 kinase protein, and a kinase substrate, (b) incubating said kinase reaction mixture in the presence and absence of a test compound for a time sufficient to permit the Nercc1 kinase protein to phosphorylate the kinase

substrate, and (c) determining the level of phosphorylated kinase substrate in the presence and absence of said test compound, wherein a lower level of phosphorylated kinase substrate produced in the presence of said test compound compared to the level produced in the absence of said test compound indicates that said test compound is an inhibitor of mitosis..

Group 2, claim(s) 17-21, drawn to the method according to claim 1 or claim 2, comprising the additional step: (d) determining whether said test compound of step (c) inhibits mitosis in dividing cells.

Claim 22 link inventions 3-6. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 22. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP ' 804.01.

Group 3, claim(s) 23-29, drawn to a method of identifying an inhibitor of mitosis comprising: (a) providing a kinase reaction mixture comprising an activated Nek6 kinase protein, a kinase substrate, and a purine nucleoside triphosphate, (b) incubating said reaction mixture in the presence and absence of a test compound for a time sufficient to permit the activated Nek6 kinase protein to phosphorylate said kinase substrate, and (c) detecting the level of phosphorylated kinase substrate in the presence and absence of said test compound, wherein a lower level of phosphorylated kinase substrate produced in the presence of said test compound compared to the level produced in the absence of said test compound indicates that said test compound is an inhibitor of mitosis.

Group 4, claim(s) 30-34, drawn to the method according to claim 22 for Nek6 kinase, comprising the additional step of determining whether said test compound inhibits mitosis in dividing cells.

Group 5, claim(s) 23-29, drawn to a method of identifying an inhibitor of mitosis comprising: (a) providing a kinase reaction mixture comprising an activated Nek7 kinase protein, a kinase substrate, and a purine nucleoside triphosphate, (b) incubating said reaction mixture in the presence and absence of a test compound for a time sufficient to permit the activated Nek7 kinase protein to phosphorylate said kinase substrate, and (c) detecting the level of phosphorylated kinase substrate in the presence and absence of said test compound, wherein a lower level of phosphorylated kinase substrate produced in the presence of said test compound compared to the level produced in the absence of said test compound indicates that said test compound is an inhibitor of mitosis.

Group 6, claim(s) 30-34, drawn to the method according to claim 22 for Nek7 kinase, comprising the additional step of determining whether said test compound inhibits mitosis in dividing cells.

Group 7, claim(s) 35-37, drawn to a method of diagnosing a cancerous or potentially cancerous state in an individual comprising: (a) assaying cells from said individual for the level of Nercc1 kinase **protein**, (b) comparing the level of Nercc1 protein determined in the cells from step (a) to the level determined in normal, non-cancerous cells or to the level determined in a prior sample of cells from said individual, wherein an elevation in the level of Nercc1 protein determined in the cells from step (a) relative to the level determined in normal, non-cancerous cells or relative to the level determined in a prior sample of cells from said individual is diagnostic for a cancerous or potentially cancerous state.

Group 8, claim(s) 35-37, drawn to a) assaying cells from said individual for the level of Nek6 kinase **protein**, (b) comparing the level of Nek6 protein determined in the cells from step (a) to the level determined in normal, non-cancerous cells or to the level determined in a prior sample of cells from said individual, wherein an elevation in the level of Nek6 protein determined in the cells from step (a) relative to the level determined in normal, non-cancerous cells or relative to the level determined in a prior sample of cells from said individual is diagnostic for a cancerous or potentially cancerous state.

Group 9, claim(s) 35-37, drawn to a) assaying cells from said individual for the level of Nek7 kinase **protein**, (b) comparing the level of Nek7protein determined in the cells from step (a) to the level determined in normal, non-cancerous cells or to the level determined in a prior sample of cells from said individual, wherein an elevation in the level of Nek7protein determined in the cells from step (a) relative to the level determined in normal, non-cancerous cells or relative to the level determined in a prior sample of cells from said individual is diagnostic for a cancerous or potentially cancerous state.

Group 10, claim(s) 35-37, drawn to a method of diagnosing a cancerous or potentially cancerous state in an individual comprising: (a) assaying cells from said individual for the level of Nercc1 **kinase activity**, (b) comparing the level of Nercc1 kinase activity determined in the cells from

step (a) to the level determined in normal, non-cancerous cells or to the level determined in a prior sample of cells from said individual, wherein an elevation in the level of Nercc1 kinase activity determined in the cells from step (a) relative to the level determined in normal, non-cancerous cells or relative to the level determined in a prior sample of cells from said individual is diagnostic for a cancerous or potentially cancerous state.

Group 11, claim(s) 35-37, drawn to a) assaying cells from said individual for the level of Nek6 **kinase activity**, (b) comparing the level of Nek6 kinase activity determined in the cells from step (a) to the level determined in normal, non-cancerous cells or to the level determined in a prior sample of cells from said individual, wherein an elevation in the level of Nek6 kinase activity determined in the cells from step (a) relative to the level determined in normal, non-cancerous cells or relative to the level determined in a prior sample of cells from said individual is diagnostic for a cancerous or potentially cancerous state.

Group 12, claim(s) 35-37, drawn to a) assaying cells from said individual for the level of Nek7 **kinase activity**, (b) comparing the level of Nek7 kinase activity determined in the cells from step (a) to the level determined in normal, non-cancerous cells or to the level determined in a prior sample of cells from said individual, wherein an elevation in the level of Nek7 kinase activity determined in the cells from step (a) relative to the level determined in normal, non-cancerous cells or relative to the level determined in a prior sample of cells from said individual is diagnostic for a cancerous or potentially cancerous state.

Although claim 35 is presented in Markush format, the claims are drawn to multiple methods using multiple agents which do not share, as a whole, a substantial structural feature disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that unity of invention exists where entities included within a Markush group share a substantial structural feature disclosed as being essential to utility of the invention, In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Since the members of the group do not share a substantial structural feature disclosed as being essential to utility of the invention, the group as claimed fails the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEP 803.02.

Group 13, claim(s) 38-45, drawn to a mutant variant Nercc1 kinase protein or fusion protein thereof that is constitutively active, wherein said mutant variant Nercc1 kinase protein or fusion protein thereof is active in the absence of phosphorylation at an activation site in said mutant variant Nercc1 kinase protein or fusion protein thereof.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when

there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The technical feature linking Groups 1-13 appears to be the modulation of the activity, function, or levels of NIMA-like kinases. A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The inventions listed as Groups 1-13 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups 1-13 appears to be the modulation of the activity, function, or levels of NIMA-like kinases.

However, Plowman et al. (WO 99/66051 A2, 23 December 1999, IDS) teach methods for identifying a substance that modulates NEK 6 kinase, see claims 14 and 15. Plowman et al. also

teach detecting altered levels of NEK kinase in a sample as an indicator of disease, see p. 51, lines 12-18.

Therefore, the technical feature linking the inventions of Groups 1-13 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Species Elections for Group 1

A. Claim 1 is generic to the following disclosed patentably distinct species of the form of Nercc1 kinase protein:

1) non-activated Nercc1 kinase

2) activated Nercc1 kinase

If applicant elects species B-2, activated Nercc1 kinase, then applicant must elect from group B

B. Claim 1 is generic to the following disclosed patentably distinct species of the form of activated, Nercc1 kinase protein and fusion proteins thereof:

1) phosphorylated Nercc1 kinase

2) a recombinantly produced, activated Nercc1 kinase

3) a constitutively active mutant variant of Nercc1 kinase

4) a recombinantly produced, activated Nercc1 kinase

If applicant elects species C-3, a constitutively active mutant variant of Nercc1 kinase, then applicant must elect from group C.

C. Claim 1 is generic to the following disclosed patentably distinct species of the form of constitutively active mutant variant of Nercc1 kinase and fusion proteins thereof:

1) Nercc1 kinase is constitutively active owing to the absence of **all** of an RCC1 auto-inhibitory domain

2) Nercc1 kinase is constitutively active owing to the absence of **a portion** of an RCC1 auto-inhibitory domain

D. Claim 1 is generic to the following disclosed patentably distinct species of the form of kinase substrate:

1) non-activated Nercc1 kinase or fusion protein thereof

2) non-activated Nek 6 kinase or fusion protein thereof

3) non-activated Nek 7 kinase or fusion protein thereof

4) histone H3 or fusion protein thereof

5) histone H4 or fusion protein thereof

6) casein or fusion protein thereof

7) myelin basic protein or fusion protein thereof

E. Claim 1 is generic to the following disclosed patentably distinct species of detecting the phosphorylated form of the kinase substrate:

1) detecting with an antibody

2) detecting with radio-labeled ^{32}P

If applicant elects species E-1, detecting with an antibody, then applicant must elect from group F.

F. Claim 1 is generic to the following disclosed patentably distinct species of the form of phosphorylated kinase substrate:

1) phosphorylated Nercc1 kinase or fusion protein thereof

2) phosphorylated Nek 6 kinase or fusion protein thereof

3) phosphorylated Nek 7 kinase or fusion protein thereof

4) phosphorylated histone H3 or fusion protein thereof, as contemplated in the specification

5) phosphorylated histone H4 or fusion protein thereof as contemplated in the specification

6) phosphorylated casein or fusion protein thereof

7) phosphorylated myelin basic protein or fusion protein thereof

G. Claim 1 is generic to the following disclosed patentably distinct species of vessels:

1) test tube

2) microtiter plate

3) biochip

4) coverslip

5) combination of 1-4

If D-5 is elected, then a specific, defined combination of vessels must be elected.

Species Elections for Group 2

A. Claim 1 is generic to the following disclosed patentably distinct species of the form of Nercc1 kinase protein:

1) non-activated Nercc1 kinase

2) activated Nercc1 kinase as contemplated in the specification

B. Claim 17 is generic to the following disclosed patentably distinct species of dividing cell types:

1) cancer cells

2) noncancerous cells, as contemplated in the specification

C. Claim 17 is generic to the following disclosed patentably distinct species of cell responses:

1) cell lysis

2) apoptosis

3) disruption of mitotic spindles

4) misalignment of chromosomes

5) combinations of 1-4

If C-5 is elected, then a specific, defined combination of cell responses must be elected.

D. Claim 17 is generic to the following disclosed patentably distinct species of vessels:

1) test tube

2) microtiter plate

3) biochip

4) coverslip

5) combinations of 1-4

If D-5 is elected, then a specific, defined combination of vessels must be elected.

Species Elections for Groups 3 and 5

A. Claim 22 is generic to the following disclosed patentably distinct species of the form of kinase substrate:

1) Cdc16 or fusion protein thereof

2) MBP or fusion protein thereof

B. Claims 22 is generic to the following disclosed patentably distinct species of vessels:

1) test tube

2) microtiter plate

3) biochip

4) coverslip

5) combinations of 1-4

If B-5 is elected, then a specific, defined combination of vessels must be elected.

C. Claim 22 is generic to the following disclosed patentably distinct species of detecting the phosphorylated form of the kinase substrate:

1) detecting with an antibody

2) detecting with radio-labeled ^{32}P

If applicant elects species C-1, detecting with an antibody, then applicant must elect from group D.

D. Claim 22 is generic to the following disclosed patentably distinct species of the form of phosphorylated kinase substrate:

1) phosphorylated Cdc16 or fusion protein thereof

2) phosphorylated MBP or fusion protein thereof

Species Elections for Groups 4 and 6

A. Claim 30 is generic to the following disclosed patentably distinct species of dividing cell types:

1) cancer cells

2) noncancerous cells, as contemplated in the specification

B. Claim 30 is generic to the following disclosed patentably distinct species of cell responses:

1) cell lysis

2) apoptosis

3) disruption of mitotic spindles

4) misalignment of chromosomes

5) combinations of 1-4

If B-5 is elected, then a specific, defined combination of cell responses must be elected.

C. Claim 30 is generic to the following disclosed patentably distinct species of vessels:

1) test tube

2) microtiter plate

3) biochip

4) coverslip

5) combinations of 1-4

If C-5 is elected, then a specific, defined combination of vessels must be elected.

Species Elections for Groups 7-12

A. Claim 35 is generic to the following disclosed patentably distinct species of diagnosed states:

1) cancerous state

2) potentially cancerous state

B. Claim 35 is generic to the following disclosed patentably distinct species of measured level:

1) protein level

2) kinase activity

If Applicant elects B-1, then applicant must elect from species in C.

C. Claim 35 is generic to the following disclosed patentably distinct species of detection methods:

1) immunodetection assay

2) transcription assay for mRNA encoding the protein of the elected Group

Claim 36 will be examined as it is drawn to the elected invention.

D. Claim 37 is generic to the following disclosed patentably distinct species of cell sources:

1) tissue biopsy

2) blood

3) cell smear

4) tissue swab

5) bodily fluid

6) feces

Species Elections for Group 13

A. Claim 38 is generic to the following disclosed patentably distinct species of variant Nercc1 kinase protein or fusion protein thereof:

1) Nercc1 kinase lacking all of an RCC1 auto-inhibitory domain/ Nercc1 (Δ347-732)

2) Nercc1 kinase lacking a portion of an RCC1 auto-inhibitory domain

3) Nercc1 (Δ763-889)

4) Nercc1 (Δ338-739)

5) Nercc1 (347-732)

6) Nercc1 (338-739)

Claims 39-40 will be examined as they are drawn to the elected invention.

B. Claims 38, 39, 42 and 42 are generic to one or more of 4 patentably distinct non-Nercc polypeptides for making fusion proteins. Applicant is required to identify and elect a

single non-Nercc polypeptide or a specific, defined combination thereof for examination, wherein the non-Nercc polypeptides are:

1) glutathione S-transferase

2) epitope tag polypeptide

If applicant elects species B-2, then applicant must elect from species group C;

C. Claims 38, 39, 42 and 42 are generic to one or more of 3 patentably distinct epitope tag polypeptides for making fusion proteins. It is noted that the number of combinations in Claim 45, 3 epitope tag polypeptides as claimed, as calculated by factorial analysis is 6, that is 3! = 6. Thus, the claims are drawn to 6 distinct inventions. Applicant is required to identify and elect a single epitope tag polypeptide or a specific, defined combination thereof for examination wherein the epitope tag polypeptides are:

1) FLAG

2) HA

3) myc

Claims 38-45 will be examined as drawn to the elected invention.

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s)

obvious under 35 USC 103. Since the decisions in *In re Weber*, 198 USPQ 328 (CCPA 1978) and *In re Hass*, 198 USPQ 334 (CCPA 1978), it is proper for the Office to refuse to examine that which applicants regard as their invention, if the subject matter in a claim lacks unity of invention, see MPEP 803.02.

Further some of the species are related as combination and subcombination. Species in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations is useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

The above species are independent or distinct because they comprise structurally distinct molecules and have different modes of operation and different effects. Further, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each species group above for the elected invention Group, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

PJR